



Innovative Medicines Initiative

European Lead Factory Topic Workshop

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Need for public-private collaboration



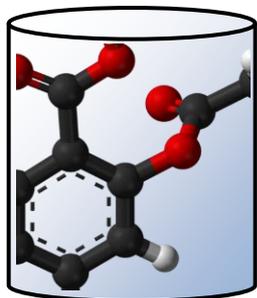
- ❑ Novel Lead Structures and Drug Targets are Innovation Drivers of the Early Small Molecule Drug Discovery Process
- ❑ Shift of Pharma discovery portfolio towards challenging (“intractable”) targets
- ❑ Limited access of academia to comprehensive compound collections and medicinal chemistry resources
- ❑ Combining strengths to enhance early drug discovery process for both, public and private projects

<i>Academia</i>	<i>Industry</i>
Knowledge Generation	Value Generation
Cutting-Edge Science	Risk-Balanced Portfolio
Multi-Disciplinary Networks	Operational Efficiency

Objectives of the full project



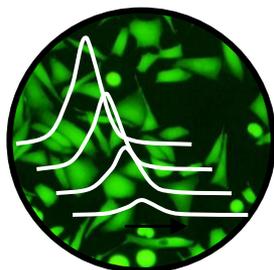
*Joint European
Compound Collection*



up to 500.000 cpds.

X

Target/Assay



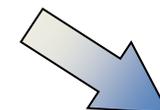
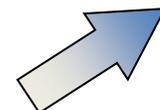
*Hit
Characterization*



*MedChem
Follow-Up*

*Qualified
Hit List*

**Hit-to-Lead
Optimization**

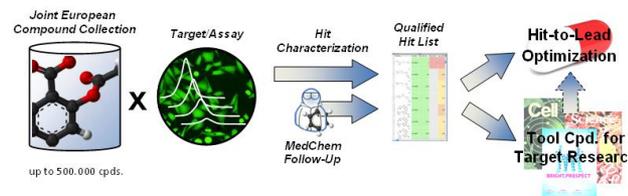


- ❑ Provide access to comprehensive, high-quality Joint EU Compound Collection
- ❑ Generate “Qualified Hits” for subsequent refinement in drug development process or serving as tool compounds in target research
- ❑ Establish novel platform to foster public-private collaboration
- ❑ Generate broad knowledge base (Qualified Hits x 240 projects) to directly exploit results or deduce future library design strategies

Objectives of the full project



The EU Lead Factory

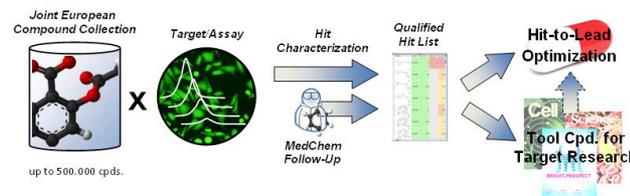


- Generate Comprehensive high-quality **Joint European Compound Collection**:
 - ◆ integrate industry's medicinal chemistry know-how
 - ◆ focus on value (IP) generation => unique, commercially non-available compounds
 - ◆ complement "Pharma Collection" by novel **Public Compound Collection**
=> (i) differentiated chemistry, (ii) targeting 'intractable targets'
- Establish **European Screening Centre** as 'Centre of Excellence' for
 - ◆ housing and managing the Joint EU Compound Collection
 - ◆ development of target or pathway-specific bioassays
 - ◆ performing HTS for public projects
 - ◆ drive experimental hit characterization (selection) process
 - ◆ managing data flow and analysis ('honest broker concept') and project execution

Objectives of the full project

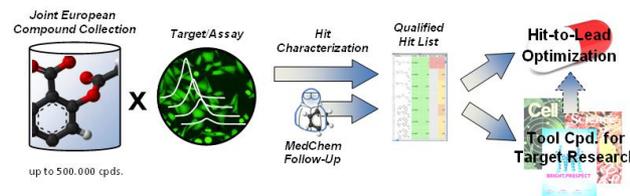


The EU Lead Factory



- ❑ Project realization within time and budget frame requires operational efficiency
- ❑ Generation of “Qualified Hits”: medchem properties to match project purpose (Lead or Tool); qualification can include also limited chemistry follow-up activities
- ❑ Preference for public projects with relevance to research focus of EFPIA consortium (early partnering) → focus on innovation: No overlap with current or past pharma portfolio
- ❑ Information management to balance Intellectual Property (IP) generation with knowledge generation: Disclosure of structural information to project owner (and ultimately public) limited to Qualified Hit List

The EU Lead Factory

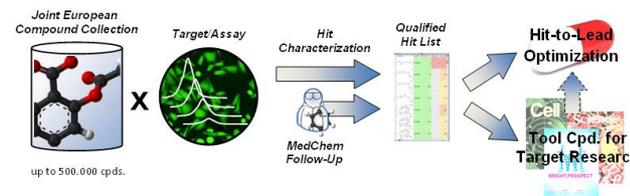


- Aims to provide industrial lead finding platform to academic programmes
 - (i) seeking quality tool compounds for target research
=> validation of novel druggable targets
 - (ii) seeking quality compound candidates to enter drug optimization process
=> exploiting also pharma collections outside industry focus for the benefit of patients
- Constitutes *'controlled experiment'* to broaden scope of pre-competitive research into early stage drug discovery : Collaborative exploitation of compound collections

Expected impact on the R&D process



The EU Lead Factory



- ❑ Ideally combines basic and applied research to translate cutting-edge research into early drug discovery programmes
- ❑ Provides platform to explore high-risk discovery approaches to share both, success stories and failures
- ❑ Provides novel aspect in pre-competitive research: Collaborative exploitation of compound collections in Screening Consortium

Suggested architecture of the project



Applicant Consortium to establish

Technology Platforms:

- ▶ *Screening Centre:* Leads or Tools
- ▶ *Library Synthesis:* Public Compound Collection

EU Lead Factory provides platforms to collect and translate academia's cutting-edge science to tangible 'qualified hits':

- ▶ *Screening Centre:* innovative discovery programs (→ target, pathway, assay) with a clear value proposition
- ▶ *Library Synthesis:* innovative library design proposals expanding chemical space through new synthetic methodologies or motifs addressing intractable targets

Expected contributions of the applicants



Compound Logistics ■ Assay Development ■
High-Throughput Screening ■ Hit Characterization ■
Medicinal Chemistry Follow-Up ■ Data
Management & Analysis ■ Project Management

▶ 48 HTS Projects *per anno*

full support for 24 public projects p.a.

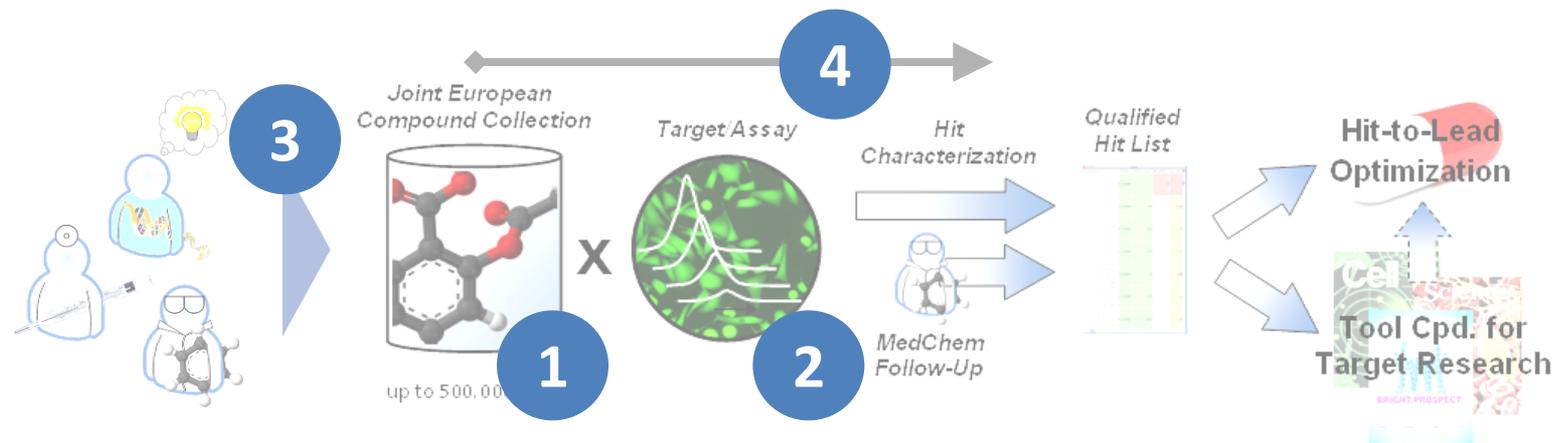
HTS for 24 private projects will be performed by EFPIA Participant

High-Throughput Chemistry ■ Compound Library
Design ■ Chemoinformatics ■ Project Management

▶ up to 200.000 novel compounds
(100.000 in the first 3 years)

▶ **Eols should address one of the 2 Sub-Topics; selected applicant groups eventually merge with EFPIA Consortium to generate Full Project Proposal**

Expected (in kind) contributions of EFPIA members



1. High quality compounds from in-house collections (from automated and medchem synthesis): 50.000 cpds. → 4 HTS p.a.
2. Execution of private projects (from assay development to HTS) by EFPIA Participant → assay data, incl. test description, will be provided to Screening Centre
3. Expertise and know-how introduced in review & selection processes (Chemical Library and HTS Project Proposals)
4. Expertise and know-how supporting efficient project realization in Screening Centre; optional provision of assays for hit characterization

What's in it for you?



Academia

- ❑ Access to industry-like small molecule discovery platform to identify quality hit compounds translating cutting-edge projects to drug discovery or target research programmes
- ❑ Access to extended expert workbench to realize innovative chemistry proposals => introduce your chemistry to broad pharmaceutical screening activities
- ❑ Funding source to translate ideas into value

SMEs

- ❑ Platform to establish early research collaborations
- ❑ Unique public-private consortium in the field of early drug discovery => focus on value (IP) generation

Patients' Organizations

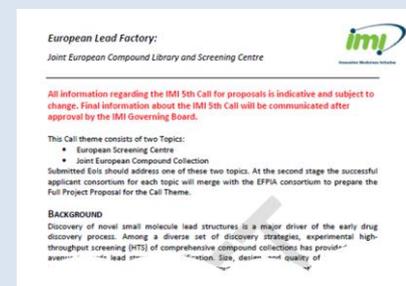
- ❑ Industry-like discovery engine for projects also outside of pharma focus (e.g. orphan diseases)

Key deliverables of the full project



- ❑ Define processes, incl. internal and external interfaces, and division of work among participants
- ❑ Elaborate detailed governance structure
- ❑ Provide detailed planning for quantitative project goals, timelines and anticipated budget
- ❑ Formulate rules for information management, IP handling, and ownership as drafted in Topic Text

within general framework described in the Topic Text:



<http://www.imi.europa.eu>

- ❑ *Identify options to compensate for funding gaps*

Questions?



- Contact the **IMI Executive Office**

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Website: www.imi.europa.eu